UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MASSACHUSETTS

IN RE PHARMACEUTICAL INDUSTRY AVERAGE WHOLESALE PRICE LITIGATION	MDL NO. 1456 CIVIL ACTION NO. 01-CV-12257-PBS
THIS DOCUMENT RELATES TO 01-CV-12257-PBS	Judge Patti B. Saris **REDACTED VERSION FOR PUBLIC FILING**

ASTRAZENECA PHARMACEUTICALS LP'S INDIVIDUAL MEMORANDUM IN OPPOSITION TO PLAINTIFFS' MOTION FOR CLASS CERTIFICATION

PRELIMINARY STATEMENT

AstraZeneca Pharmaceuticals LP ("AstraZeneca") respectfully submits this memorandum of law in further support of its opposition to plaintiffs' motion for class certification. For all of the reasons stated in the Track 1 Defendants' Memorandum in Opposition to Class Certification, none of the plaintiffs' proposed classes can be certified under Rule 23 – even if the proposed classes related to just one defendant. In the case of the proposed Third-Party Payor Class and RICO subclass, it is clear that an AstraZeneca-specific class would fail to satisfy the requirements of Rule 23, because individual class member issues would continue to predominate for the reasons stated in the Track 1 Defendants' Memorandum and because a drug-by-drug analysis of the sixteen non-Part B AstraZeneca drugs listed in the complaint would still be required to determine liability.

Indeed, plaintiffs have indiscriminately lumped the AstraZeneca drugs identified in the AMCC together, notwithstanding the fact that they are administered and reimbursed in different ways, face different types of competition, and operate in different markets. The unavoidable consequence of these facts (which are ignored by plaintiffs) is that the myriad of individualized issues that would have to be addressed in order to adjudicate plaintiffs' claims would overwhelm any common issues and destroy any perceived efficiency from the class action mechanism.

In the case of AstraZeneca's lone Part B drug, Zoladex® (goserelin acetate), class certification would still be precluded for all the reasons cited in the Track 1 Defendants' Memorandum. In addition, there is no typical or adequate representative among the named plaintiffs with respect to Zoladex. Accordingly, plaintiffs' motion for class certification should be denied.

FACTUAL BACKGROUND

Plaintiffs have listed seventeen drugs in Appendix A to the AMCC. Only one of these seventeen is potentially implicated by the proposed Medicare Part B Co-Payor Class: Zoladex, an

injectable physician-administered drug primarily used in the palliative treatment of advanced prostate cancer. In comparison, the scope of the Third Party Payor Class when applied to AstraZeneca dwarfs the Medicare Part B Co-Pay Class by several orders of magnitude. Sixteen additional drugs are potentially at issue from many of the major therapeutic categories, including:

- oncology -- Arimidex® (anastrozole) and Nolvadex® (tamoxifen citrate) (for breast cancer) and Casodex® (bicalutamide) (for prostate cancer);
- cardiovascular products -- Atacand® (candesartan cilexetil) and Atacand HCT® (candesartan cilexetil-hydrochlorothiazide), Toprol-XL® (metoprolol succinate), and Zestril® (lisinopril) (for hypertension and heart failure);
- gastrointestinal products -- Entocort® (budesonide) (for treatment of Crohn's disease), and Prilosec® (omeprazole) and Nexium® (esomeprazole magnesium) (for treatment of gastroesophageal reflux disease and esophagitis)
- neuroscience -- Diprivan® (propofol) (injectable general anesthetic), Seroquel® (quetiapine fumarate) (for treatment of schizophrenia and bipolar disorder), and Zomig® (zolmitriptan) (for treatment of migraines); and
- respiratory -- Accolate® (zafirlukast) and Pulmicort® (budesonide inhalation powder) (for treatment of asthma) and Rhinocort® (budesonide) (for treatment of allergic rhinitis).

See AMCC ¶ 231.

As demonstrated below, these drugs compete in very different markets under very different competitive circumstances and are priced and reimbursed in a variety of ways, creating individual issues relating to liability that predominate over any common issues.

ARGUMENT

I. Plaintiffs' Proposed Third Party Payor Classes Fail to Satisfy the Requirements of Rule 23(b)(3) with Respect to AstraZeneca

Plaintiffs have acknowledged that "whether or not a given AWP is reliable or inflated by the scheme is discovered on a drug-by-drug basis." Plaintiffs' Opposition to Amgen's Motion to Dismiss AMCC at 5. Thus, even assuming that plaintiffs can establish that the published AWP for a single one of the seventeen AstraZeneca products at issue was "fraudulently inflated" at a single point in time, that proof is not sufficient with respect to the other sixteen drugs or even with respect that single drug at other points in time over the proposed thirteen-year time period. *See, e.g., Sloan v. C.C. Collings & Co.*, 1986 U.S. DIST. LEXIS 21632 at *2-3 (E.D. Pa. Aug. 12, 1986) ("Any inquiry into alleged excessive prices charged by the defendants must proceed on an individual basis for each municipal security purchased by each proposed class member at each point in time."). This drug-by-drug inquiry would be required in addition to the individualized, customer-by-customer inquiry required to that the alleged "fraud" had any effect on reimbursement.

This conclusion is borne out by the evidence developed to date. AstraZeneca's Senior Director of Contract Strategy testified that AstraZeneca's pricing, rebating and discounting practices varied drug-by-drug and trade class-by-trade class, and depended on a wide range of factors including each drug's competitive environment and each drug's clinical performance. (Alverson Tr. at 59, 94, 108, 125-38, 142-44, 254 (attached hereto as Exhibit A).) Indeed, negotiations are often done on a drug-by-drug basis, even with the same entity. (Alverson Tr. at 59.) Moreover, the practices can change over time even for a single drug, from the time it is new to the market to when it faces generic competition because patent exclusivity has expired. (*Id.* at 137-38, 142-44.)

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At least one drug is not even reimbursed through a PBM; Diprivan, an injectable anesthetic, is only used by hospitals, (*Id.* at 130), perhaps explaining why not one of the named plaintiffs has made payments for the drug, *see* AMCC Appendix B.

Thus, on top of the individualized inquiry that would be required with respect to each of the putative class members, *see* Track 1 Defendants' Memorandum at 19-35, the Court would also be required to engage in an extensive inquiry on a drug-by-drug basis over time in order to determine AstraZeneca's liability to the proposed classes. This process would create "an overwhelming deluge of mini-trials" that would render any trial utterly unmanageable. *Windham v. American Brands*, 565 F.2d 59, 67 (4th Cir. 1977); *cf. Buckhalter Travel Agency v. MacFarms Int'l, Inc.*, 141 F.R.D. 144, 154 (N.D. Cal. 1991) (denying class certification because the differences in the macadamia-nut industry served to create more individual issues than common: "there are significant differences between the markets for macadamia nuts on Hawaii and on the mainland, between large and small purchasers, and between bulk and retail purchasers. In these different markets,

defendants price nuts in different ways and purchasers have varying degrees of leverage over defendants.").

Plaintiffs gloss over these complications in their motion for class certification. *See* Plaintiffs' Memorandum in Support of Class Certification at 15-16 (hereinafter "Pl. Mem."). Plaintiffs first assert that they can efficiently establish that each defendant report "fraudulently inflated" AWPs through their expert's analysis of each defendant's data. However, as more fully explained in the Track 1 Defendants' Memorandum in Support of Motion to Strike the Declaration of Raymond S. Hartman, this "expert" analysis is unreliable, inadmissible and does nothing to establish any defendant's liability to the class. In addition, the large "spreads" that plaintiffs rely on with respect to AstraZeneca's drugs, *see* Hartman Decl. at Table 2A; Pl. Mem. at 15-16, are themselves artificially inflated, because Dr. Hartman apparently included sales to irrelevant trade classes, as well as rebates that actually pass through to the third party payors in the putative classes, *reducing* their net cost of reimbursement. *See* Memorandum in Support of Motion to Strike at 12-15.

Plaintiffs also assert that they will corroborate this analysis with documentary evidence from AstraZeneca's own records. *See* Pl. Mem. at 15-16. Yet most of the documents they cite relate to Zoladex, a Part B Drug irrelevant to the claims being asserted by the proposed Third Party Payor classes. *See* Declaration of Steve W. Berman in Support of Plaintiffs' Motion for Class Certification at 4-6 and Exhs. 74-82. Moreover, the two documents plaintiffs cite that do not relate to Zoladex do not support plaintiffs' theory and only emphasize that an intensive drug-by-drug inquiry will be necessary to establish plaintiffs' claims. *See* Berman Decl. at 6-7. For example, plaintiffs cite a document relating to the pricing of Nexium as support for the allegation that AstraZeneca's strategy was to set a high AWP to advantage PBMs. *Id.*

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Not only does this document fail to demonstrate fraud with respect to Nexium, it establishes nothing with respect to any other drug.

II. There is No Typical or Adequate Representative of a Medicare Part B Co-Payor Class Relating to Zoladex

Of the seventeen pharmaceutical products manufactured by AstraZeneca that were allegedly purchased by plaintiffs, Zoladex is the only drug relevant to the proposed Medicare Part B Co-Payor Class. Only one named plaintiff, Teamsters Health & Welfare Fund ("THWF"), is alleged to have made reimbursements for Zoladex. *See* AMCC at Appendix B. Yet, the evidence is clear that at no point during the class period has THWF covered or reimbursed its plan beneficiaries for Medicare Part B co-payments for Zoladex or any other drug. As William J. Einhorn, the plan administrator for THWF testified:

Q: How long has the fund been providing pharmaceutical benefits?
A: To my knowledge, and this – it could precede me and my knowledge, but I know from at least 1979.
Q: [ ] What was your understanding of how providers are reimbursed under Medicare Part B?
A: I do not have any responsibility or knowledge as to how providers are reimbursed under Medicare Part B, other than some very general knowledge that there is a Medicare limit and providers are reimbursed on a fee for service basis up to that limit.
Q: Does the fund pay all or any portion of the co-pay that a Medicare Part B beneficiary may have to pay for an administered pharmaceutical?
A: No, we don't provide benefits to retirees at all.
Q: [ ] There are people besides retirees who might be eligible for Medicare Part B benefits?
A: Disabled individuals who would be disabled for more than a 24 month period of time. That means they would be out of covered employment and that means they would not have any eligibility with us, so we would not have any role in that.
Q: There is no situation in which the fund would cover a Medicare Part B co-payment?
A: No, not to my knowledge.

(Einhorn Tr. at 76-77 (SJY Vol. II. A.).)

It necessarily follows that any claims THFW has relating to Zoladex cannot be typical of the claims of either the individual beneficiaries or institutional payors in the Medicare Part B Class, who by definition, made Medicare Part B co-payments. Indeed, plaintiff THWF is not even a member of the class it purports to represent. Accordingly, plaintiffs cannot satisfy the requirement of Rule 23(a)(3) and (4), *see In re American Med. Sys., Inc.,* 75 F.3d 1069 (6th Cir. 1996); *In re Polymedica Corp. Sec. Litig.*, 224 F.R.D. 27, 36 (D. Mass. 2004), and no Medicare Part B Co-Payor class can be certified with respect to AstraZeneca.

CONCLUSION

For the reasons set forth above and in the Track 1 Defendants Memorandum, Plaintiffs' Motion for Class Certification should be denied.

Dated: Boston, Massachusetts
October 25, 2004

Respectfully Submitted,

By: /s/

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CERTIFICATE OF SERVICE

I certify that on October 25, 2004, a true and correct copy of the foregoing Memorandum in Opposition to Plaintiffs' Motion for Class Certification was served on all counsel of record by express mail.

/s/
Lucy Fowler

CERTIFICATE OF SERVICE

I hereby certify that on November 3, 2004, I caused a true and correct copy of AstraZeneca Pharmaceuticals LP's Individual Memorandum in Opposition to Plaintiffs' Motion for Class Certification [REDACTED VERSION] and the accompanying Declaration of Stuart Fullerton to be served on all counsel of record by electronic service pursuant to Case Management Order No. 2.

/s/ Jessica V. Barnett
Jessica V. Barnett